

a device intended to measure the activity of angiotensin converting enzyme in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of diseases such as sarcoidosis, a disease characterized by the formation of nodules in the lungs, bones, and skin, and Gaucher's disease, a hereditary disorder affecting the spleen.

(b) *Classification.* Class II.

§ 862.1095 Ascorbic acid test system.

(a) *Identification.* An ascorbic acid test system is a device intended to measure the level of ascorbic acid (vitamin C) in plasma, serum, and urine. Ascorbic acid measurements are used in the diagnosis and treatment of ascorbic acid dietary deficiencies.

(b) *Classification.* Class I.

§ 862.1100 Aspartate amino transferase (AST/SGOT) test system.

(a) *Identification.* An aspartate amino transferase (AST/SGOT) test system is a device intended to measure the activity of the enzyme aspartate amino transferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

(b) *Classification.* Class II.

§ 862.1110 Bilirubin (total or direct) test system.

(a) *Identification.* A bilirubin (total or direct) test system is a device intended to measure the levels of bilirubin (total or direct) in plasma or serum. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, if used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

(b) *Classification.* Class II.

§ 862.1113 Bilirubin (total and unbound) in the neonate test system.

(a) *Identification.* A bilirubin (total and unbound) in the neonate test system is a device intended to measure the levels of bilirubin (total and un-

bound) in the blood (serum) of newborn infants to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

(b) *Classification.* Class I.

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§ 862.1115 Urinary bilirubin and its conjugates (nonquantitative) test system.

(a) *Identification.* A urinary bilirubin and its conjugates (nonquantitative) test system is a device intended to measure the levels of bilirubin conjugates in urine. Measurements of urinary bilirubin and its conjugates (nonquantitative) are used in the diagnosis and treatment of certain liver diseases.

(b) *Classification.* Class I.

§ 862.1120 Blood gases (P_{CO2}, P_{O2}) and blood pH test system.

(a) *Identification.* A blood gases (P_{CO2}, P_{O2}) and blood pH test system is a device intended to measure certain gases in blood, serum, plasma or pH of blood, serum, and plasma. Measurements of blood gases (P_{CO2}, P_{O2}) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

(b) *Classification.* Class II.

§ 862.1130 Blood volume test system.

(a) *Identification.* A blood volume test system is a device intended to measure the circulating blood volume. Blood volume measurements are used in the diagnosis and treatment of shock, hemorrhage, and polycythemia vera (a disease characterized by an absolute increase in erythrocyte mass and total blood volume).

(b) *Classification.* Class I.

§ 862.1135 C-peptides of proinsulin test system.

(a) *Identification.* A C-peptides of proinsulin test system is a device intended to measure C-peptides of proinsulin levels in serum, plasma, and urine. Measurements of C-peptides of proinsulin are used in the diagnosis and treatment of patients with abnormal insulin secretion, including diabetes mellitus.

(b) *Classification.* Class I.